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**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**SANDRA WHITE, on behalf of
JORDAN WHITE**
68 Bryn Mawr Ave.,
Lansdowne, PA 19050

Plaintiff,

v.

MEDTRONIC, INC.
710 Medtronic Parkway,
Minneapolis, Minnesota 55432;

**MEDTRONIC
NEUROMODULATION,
a division of Medtronic, Inc.**
7000 Central Avenue NE,
Fridley, Minnesota 55432;

**MEDTRONIC PUERTO RICO
OPERATIONS, INC.;**
Ceiba Norte Industrial Park Road 31, Km. 24,
HM 4 Call Box 4070,
Junco 00777-4070, Puerto Rico;

and

Case No. _____

COMPLAINT

JURY TRIAL DEMANDED

MEDTRONIC LOGISTICS, LLC,
710 Medtronic Parkway,
Minneapolis, Minnesota 55432

Defendants.

COMES NOW, Plaintiff Sandra White, on behalf of Jordan White, by and through her undersigned attorneys, and hereby files this Complaint against the above-named Defendants, Medtronic, Inc.; Medtronic Neuromodulation, a division of Medtronic, Inc.; Medtronic Puerto Rico Operations, Inc.; and Medtronic Logistics, LLC (collectively “Defendants” or “Medtronic”), and states and alleges as follows:

I. INTRODUCTION

1. This is a products liability action seeking damages for personal injuries sustained by Jordan White arising from his use of a defective product designed, manufactured, labeled, and distributed, or otherwise placed into the stream of commerce by Defendants and/or each of them. As set forth herein, Mr. White suffered severe and permanent injuries and hospitalization as a foreseeable, direct and proximate result of defects in his Medtronic SynchroMed® II Programmable Implantable Infusion Pump System for intrathecal drug delivery, which were implanted in his abdomen. Sandra White, in her capacity as Durable Power Attorney for her son, Jordan White, brings this action on behalf of Jordan White to recover for the damages caused by Defendants’ conduct.

II. THE PARTIES, JURISDICTION, AND VENUE

2. Plaintiff Sandra White is a citizen of Pennsylvania and resides in Lansdowne, Pennsylvania. Sandra White is the natural parent of Jordan White and Durable Power of

Attorney for Jordan White, and commences this action in her capacity as Durable Power of Attorney for Jordan White.¹

3. Jordan White is a citizen of Pennsylvania and resides in Lansdowne, Pennsylvania.

4. At all times relevant hereto, Defendant Medtronic, Inc., was and is a corporation or other business entity with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432, and was involved in the design and/or assembly and/or manufacture and/or testing and/or packaging and/or labeling and/or marketing and/or distribution and/or sale and/or promotion and/or was otherwise involved in the placing in the stream of commerce medical devices and a device specifically called the SynchroMed® II Programmable Implantable Infusion Pump System (hereinafter referred to as “SynchroMed® II Device”).²

5. At all times relevant hereto, Defendant Medtronic Neuromodulation, a division of Medtronic, Inc., was and is a corporation or other business entity with its principal place of business at 7000 Central Avenue NE, Fridley, Minnesota 55432, and was involved in the design and/or assembly and/or manufacture and/or testing and/or packaging and/or labeling and/or marketing and/or distribution and/or sale and/or promotion and/or was otherwise involved in the placing in the stream of commerce medical devices and the SynchroMed® II Device.

6. At all times relevant hereto, Defendant Medtronic Puerto Rico Operations Co., was and is a corporation or other business entity and a wholly owned subsidiary of Defendant Medtronic, Inc., with its principal place of business in Ceiba Norte Industrial Park Road 31, Km. 24, HM 4 Call Box 4070, Junco 00777-4070, Puerto Rico, and was involved in the design and/or

¹ Durable Power of Attorney, attached as Exhibit 1.

² The term “SynchroMed II Device” includes the intrathecal sutureless catheter.

assembly and/or manufacture and/or testing and/or packaging and/or labeling and/or marketing and/or distribution and/or sale and/or was otherwise involved in placing in the stream of commerce medical devices and the SynchroMed® II Device.

7. At all times relevant hereto, Defendant Medtronic Logistics, LLC, was and is a limited liability corporation or other business entity and wholly owned subsidiary of Defendant Medtronic, Inc., with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432, and was involved in the design and/or assembly and/or manufacture and/or testing and/or packaging and/or labeling and/or marketing and/or distribution and/or sale and/or was otherwise involved in placing in the stream of commerce medical devices and the SynchroMed® II Device.

8. At all times relevant to this action, Defendants were authorized to do business within the Commonwealth of Pennsylvania, and manufactured, supplied, distributed, formulated, prescribed, marketed, and sold or otherwise placed into the stream of commerce the SynchroMed® II Device within the Commonwealth of Pennsylvania.

9. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, as all parties are citizens of different states and the amount in controversy exceeds the sum or value of \$75,000, exclusive of interests and costs.

10. Venue is proper pursuant to 28 U.S.C. § 1391(b), as a substantial part of the events or omissions giving rise to this action occurred in this judicial district.

III. FACTUAL ALLEGATIONS

11. Jordan White is a twenty-four (24) year old man and the natural son of Plaintiff Sandra White.

12. Jordan White suffered serious injuries from a malfunctioning and defective SynchroMed® II Device that was designed, tested, manufactured, produced, processed, assembled, inspected, distributed, marketed, labeled, promoted, packaged, advertised for sale, placed in the stream of commerce, and sold or otherwise provided to Mr. White by the Defendants.

13. Mr. White's injuries proximately resulted from the negligent and/or reckless and/or other wrongful acts and omissions, and fraudulent representations of Defendants and/or each of them, all of which occurred within the jurisdiction of this Court.

14. As a child, Mr. White was diagnosed with cerebral palsy. In order to reduce muscle spasticity associated with his condition, Mr. White was persuaded to have a SynchroMed® II Device implanted in his abdomen to administer baclofen into the intrathecal space of his spine.

15. On February 5, 2010, Mr. White had a SynchroMed® II Device, comprised of a Model #8637-40 pump (Serial #NGV435045H) and an 80 cm InDura 8709SC Intrathecal Catheter (Lot #N237977012), implanted in his body. The SynchroMed® II Device implanted in his body was intended to deliver a programmed amount of baclofen medication into his spine, reducing or eliminating the need for oral medications.

16. For several months after Mr. White had his SynchroMed® II Device implanted, his spasticity improved intermittently. However, by early 2012, the efficacy of the SynchroMed® II Device had started to noticeably decrease, as Mr. White began experiencing increased muscle tightness, rigidity, and pain, leading to significantly decreased mobility.

17. Accordingly, Mr. White's physician recommended that his SynchroMed® II Device be fully interrogated to determine whether his SynchroMed® II Device was operating

properly. In July 2012, after review of laboratory and radiographic studies, it was determined that his SynchroMed® II Device had malfunctioned due to occlusion of his intrathecal catheter, and Mr. White's physicians recommended that he undergo replacement of his intrathecal catheter.

18. On August 1, 2012, Jordan White underwent a procedure to replace the intrathecal catheter of his SynchroMed® II Device. The operative finding was a "malfunctioning intrathecal portion of pump." The malfunctioning intrathecal catheter was replaced with a Medtronic InDura 8709SC Intrathecal Catheter. Mr. White was hospitalized for seven (7) days thereafter, with postoperative pain, immobility, and severe nausea.

19. Over the next year and a half, Mr. White noticed decreased efficacy of his SynchroMed® II Device, leading again to rigidity, tightness, and pain in his extremities and further decreasing his mobility, among other complications. As a result, his physicians recommended that his baclofen be titrated and reassessed.

20. Ultimately, it was determined that his intrathecal catheter had again malfunctioned and Mr. White was not receiving the appropriate programmed dose of baclofen. On May 29, 2014, Mr. White underwent a procedure to remove his defective and malfunctioning SynchroMed® II Device.

21. During the procedure, Jordan White's intrathecal catheter was found to be fractured and broken at 35 cm. The surgeon extracted the various pieces of the broken catheter from Mr. White's body and removed his pump.

22. The continuous malfunctions and defects in Mr. White's SynchroMed® II Device resulted in severe pain, tightness, rigidity, and lack of mobility, which continues through present day. The continuous malfunctions and defects in Mr. White's SynchroMed® II Device rendered

the Device inefficacious and led to Mr. White not receiving the appropriate programmed dose of baclofen medication.

23. As a result of the aforementioned defects and malfunctions, Jordan White's defective SynchroMed® II Device failed to deliver the prescribed medication as programmed. These defects and malfunctions resulted in the medication delivered intermittently, medication "dumps" delivering too much medication, or a complete failure to deliver medication, causing severe damage and injury to Mr. White.

24. In addition, Mr. White's defective and malfunctioning SynchroMed® II Device necessitated multiple removal and replacement surgeries. The removal of the defective device and replacement of a new device is a serious, invasive, and dangerous procedure.

25. Throughout the history of the manufacture of the SynchroMed® II Device, the U.S. Food & Drug Administration (FDA) has repeatedly notified Medtronic that their manufacture of the SynchroMed® II Device failed to conform to manufacturing requirements enumerated in federal regulations and statutes. These federal violations caused the defects and malfunctions in Jordan White's SynchroMed® II Device, which caused his injuries and damages alleged herein

26. Throughout the history of the manufacture of the SynchroMed® II Device, Medtronic has shown an indifference to federal manufacturing requirements. Further, Medtronic, with full knowledge that they were manufacturing the SynchroMed® II Device in violation of law, nonetheless demonstrated a pattern of delayed responses or complete failures to respond to reported and known safety issues with the SynchroMed® II Device.

27. Because of Medtronic's years-long pattern of indifference to regulatory authority, noncompliance with federal manufacturing requirements, and violations of federal law, the U.S.

Department of Justice and the U.S. Department of Health and Human Services on April 27, 2015 filed a Complaint against Medtronic requesting a Consent Decree for Permanent Injunction against the manufacture, distribution, and sale of the SynchroMed® II Device.

28. As a foreseeable, direct and proximate result of Medtronic's conduct described herein, Jordan White has suffered and will continue to suffer damages, including lost wages and benefits, diminished wages and future earnings, mental anxiety and anguish, loss of self-esteem, and medical bills in amounts to be proven at trial.

A. The SynchroMed® II Device

29. The SynchroMed® II Device is a programmable drug infusion system implanted in the body for drug delivery. The SynchroMed® II Device includes an infusion pump connected to a thin, flexible catheter attached to the intrathecal space (spinal canal) of the patient, into which the Device delivers medication. The relevant SynchroMed® II Device was used to administer baclofen to Jordan White.

30. The SynchroMed® II Device is a Class III medical device, approved by the FDA through the Pre-Market Approval (PMA) process in 1988. Since the initial approval under PMA 860004, Medtronic sought FDA approval of at least one hundred ninety-one (191) supplements or changes to the originally-approved Device.

31. The pump of the SynchroMed® II Device is supplied in twenty (20) and forty (40) ml reservoir sizes, Models #8637-20 and 8637-40 respectively, and the Device is approved solely for the following uses:

- a. the chronic epidural/intrathecal infusion of Infumorph (preservative-free morphine sulfate sterile solution) and Prialt® (preservative-free ziconotide sterile solution) for the management of pain;

- b. the chronic intrathecal infusion of Baclofen (Lioresal) for the management of severe spasticity; and
- c. the chronic intravascular infusion of floxuridine (FDUR) and methotrexate for the treatment of primary or metastatic cancer.

32. The entire SynchroMed® II Device is implanted and remains under the skin. A clinician measures a precise amount of medication and injects the medication into the pump's reservoir fill port. The medication passes through a reservoir valve and into the pump reservoir. At normal body temperatures, pressurized gas, used as a propellant, is stored below the reservoir and it expands and exerts constant pressure on the reservoir. This pressure pushes the medication into the pump tubing. The battery-powered electronics and motor gears deliver a programmed dose of medication through the tubing out through a catheter port and into a catheter. Medication delivery then continues through the catheter tubing and into the intrathecal space of a patient.

33. The intrathecal catheters and sutureless revision kits of the SynchroMed® II Device are designed to connect the pump with the patient's intrathecal space. Each catheter has a pre-attached strain relief sleeve, a connector pin, and a sutureless pump connector that connects to the SynchroMed® II pump.

34. In their marketing, Medtronic represented the SynchroMed® II Device as "safe effective, reliable medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, including the controlled release of Morphine for the treatment of patients suffering from chronic and severe pain."

35. Medtronic marketed the SynchroMed® II Device directly to patients through conversations with Medtronic employees, patient testimonials, and colorful brochures with

images of individuals smiling and pain medication patients riding motorcycles. Medtronic's representations to patients include:

- a. "a safer way to receive pain medication";
- b. "help you rejoin life so you can get back to the activities and people that make you happiest";
- c. "allows you to 'Tame your Pain' ";
- d. "reduce your need for oral pain medications";
- e. "provide peace of mind knowing that you've selected a drug delivery system that was manufactured by Medtronic . . ."
- f. "give reassurance because only Medtronic offers a programmable drug delivery system that is FDA approved for MRI scans . . .";
- g. "increase your confidence when you consider that more than 150,000 people worldwide have used Medtronic drug delivery therapy to manage their chronic pain";
- h. "drug delivery therapy from Medtronic is a *proven safe and effective therapy*";
- i. "Medtronic drug delivery therapy has been tested, is shipped sterile, and is FDA approved"; and
- j. "more doctors trust Medtronic than any other company offering drug delivery therapy."

B. FDA Pre-Market Approval (PMA) of the SynchroMed® II Device

36. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III medical devices are those that 1) support or sustain human life, 2) are of substantial importance in preventing

impairment of human health, or 3) which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, these devices require a premarket approval (PMA) application under Section 515 of the Federal Food Drug and Cosmetic Act (FD&C Act) before they can be sold in the United States. As mentioned, the SynchroMed® II Device is a Class III medical device.

37. In a PMA application, the applicant is required to supply information to the FDA. The information required includes: a) device description, b) clinical safety trials, c) methods of its product testing, d) design of the device and specific manufacturing controls, e) outcome evaluation, and f) proposed labeling. The FDA does not conduct independent testing on a medical device in a PMA application. The FDA reviews the documentation provided to them by the PMA applicant and relies on the veracity of the company. The PMA applicant (in this circumstance, Medtronic) is solely responsible for submitting all truthful and necessary documentation to the FDA.

38. Once an application for PMA is approved, the holder (Medtronic) must comply with any and all post approval requirements established by the FDA and federal regulations. The legal requirements include but are not limited to: post marketing monitoring, evaluating and reporting adverse events, and compliance with Current Good Manufacturing Practices (CGMPs). Regulations prohibit the PMA holder from selling an adulterated or misbranded product, and prohibit promoting a device for unapproved uses.

39. In particular, federal regulations require a PMA applicant such as Medtronic to comply with the following requirements:

- a. Review, evaluate, and report to the FDA, adverse events associated with the medical device.**

- i. Report individual adverse events within thirty (30) days after becoming aware of an adverse event or aware of a reportable death, serious injury or malfunction (21 C.F.R. § 803.10(c)(1)), and
 - ii. Report individual adverse events no later than five (5) work days after becoming aware of “a reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health . . .” (21 C.F.R. § 803.10(c)(2)(i)).
- b. **Quality System.** Establish and maintain a quality system that is appropriate for the specific medical devices designed or manufactured and that meets the requirement of this part. (21 C.F.R. § 820.5).
- c. **Management Responsibility.** Management with executive responsibility shall establish its policy and objectives for, and commitment to quality. (21 C.F.R. § 820.20).
- d. **Qualified Personnel.** Have sufficient personnel with the necessary educational background, training, and experience to assure that all activities required by this part are correctly performed. (21 C.F.R. § 820.25).
- e. **Corrective and Preventative Action (CAPA).** Establish and maintain procedures for implementing corrective and preventive action, and document all activities under this section. (21 C.F.R. § 820.100).
- f. **Complaint Files.** Maintain complaint files, processed in a uniform and timely manner, oral complaints must be documents and must be evaluated to determine whether the complaint represents a reportable event under Medical Device Reporting. (21 C.F.R. § 820.198).

- g. Statistical Techniques.** Establish and maintain procedures for identifying valid statistical techniques required for establishing controlling and verifying the acceptability of process capability and product characteristics. (21 C.F.R. § 820.250).
- h. Misbranded Drugs and Devices Prohibited.** A device shall be deemed to be “*misbranded*” if its label is false or misleading in any particular. (21 C.F.R. § 820, *et al.*).
- i. Adulterated Products Prohibited.** If the manufacturer fails to ensure that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with applicable requirements, including but not limited to the Current Good Manufacturing Practice (CGMP) requirement of the Quality System regulations found at Title 21 Code of Federal Regulations Section 820, then such products are considered “*adulterated.*” (21 U.S.C. § 351 (h) (emphasis added).
- j. Prohibition of Off-Label Promotion.** A product may not be manufactured packaged, stored, labeled, distributed, advertised, or promoted in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device. (21 C.F.R. § 814.80).

C. Violations of federal law resulting in Jordan White’s defective and malfunctioning catheter

40. Medtronic, in their manufacture of the SynchroMed® II Device, violated federal law governing manufacture and quality control of PMA medical devices, which was discovered during a series of inspections by the FDA at Medtronic’s catheter manufacturing and quality control plants in Minneapolis, Minnesota and Puerto Rico.

41. The inspections were followed by a series of Warning Letters to Medtronic that identify federal manufacturing and quality control violations at the plants that ultimately led to an April 27, 2015 Complaint Requesting a Permanent Injunction filed against Medtronic by the U.S. Department of Justice and U.S. Department of Health and Human Services, and a Court-Ordered Consent Decree imposing a moratorium on the manufacture, sale, and distribution of the SynchroMed® II Device in violation of federal law.³

42. The Warning Letters, agency action, and Court Order, which include specific references to the intrathecal catheters, speak to the seriousness of Defendants' violations of federal law and general negligence in the manufacture of the SynchroMed® II Device.

43. In a 2006 Warning Letter, after an inspection of Medtronic's manufacturing plant located at 800 53rd Avenue NE, Minneapolis, Minnesota, the FDA identified "Significant Deviations" from CGMPs committed by Medtronic while manufacturing their catheters, including the failed intrathecal catheters implanted in Jordan White's body. The FDA found that, given these "significant deviations," the catheters manufactured, marketed, sold, and used in the SynchroMed® II Device were "**adulterated**" devices. These "significant deviations" include, but are not limited to, the following:

- a. Failure to implement procedures to ensure that a device's design input requirements are appropriate and address its intended use, including user/patient needs (21 C.F.R. § 820.30(c)) in that design input work for intrathecal catheter Model #8731 has not resulted in development of a complete design specification for the Platinum Iridium (Pt/Ir) catheter tip bond;

³ Complaint for Permanent Injunction, attached as Exhibit 2.

- b. Failure to conduct design validation using production units or their equivalents in that design validation testing of the intrathecal catheter Model #8731 was conducted with catheters manufactured with a Pt/Ir tip marker bonding process that was different than used in production. (21 C.F.R. § 820.30);
- c. Failure to validate a process whose results cannot be fully verified by subsequent inspections and tests, as bonding process for the Pt/Ir catheter has not been validated. (21 C.F.R. § 820.75(a));
- d. Failure to control production processes to ensure that a device conforms to its specification. (21 C.F.R. § 820.70(a));
- e. Failure to implement corrective and preventive action procedures addressing the investigation of the cause of nonconformities. (21 C.F.R. § 820.100(a)(2));
- f. Failure to implement changes in methods and procedures needed to correct and prevent identified quality problems. (21 C.F.R. § 820.100(a)(5));
- g. Failure to identify all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems. (21 C.F.R. § 820.100(a)(3)); and
- h. Failure to implement procedures to ensure that device history records for each batch, or unit are maintained to demonstrate that the device is manufactured in accordance with regulations. (21 C.F.R. § 820.184).

The FDA Warning Letter continued: “*The specific violations noted in this letter and the Form FDA-483 . . . may be symptomatic of serious underlying problems in your firm’s manufacturing quality assurance systems.*”⁴

⁴ August 29, 2006 FDA Warning Letter and Form FDA 483, dated January 24, 2007, attached collectively as Exhibit 3.

44. The FDA inspected the same Minneapolis Medtronic facility less than a year later, and on July 3, 2007 issued *another* Warning Letter concerning the SynchroMed® II Device. The FDA again warned Medtronic that their devices manufactured at the Minneapolis facility were “*adulterated*” and “*misbranded*.” A partial list of the violations the FDA found during the 2007 inspection includes:

- a. Medtronic failed to implement complaint handling procedures to ensure that all complaints are evaluated to determine whether the complaint represents an event that must be filed as a Medical Device Report (MDR).
- b. Medtronic failed to enter several medical and/or scientific literature articles discussing adverse events relating to devices the plant manufactured in the reporting system and failed to evaluate whether the adverse event related articles were required to be reported to the FDA under 21 C.F.R. § 803.50.
- c. Medtronic failed to submit MDR reports within thirty (30) days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury (21 C.F.R. § 803.50(a)(1)). Specifically, Medtronic:
 - i. Failed to report SynchroMed® II Device’s intrathecal catheters associated with granuloma or inflammatory masses at or near the distal tip, which the FDA considers “serious injuries”;
 - ii. Failed to report SynchroMed® II Device’s intrathecal catheter fractures;
 - iii. Failed to report a malfunction MDR, required when a marketed device malfunction would likely cause or contribute to a reportable death or serious injury;

- iv. Failed to submit MDR reports within thirty (30) days of learning of a problem (pump malfunctions, catheter fracture or separation, inflammatory masses and granulomas) of Medtronic's device in the literature;
- v. Failed to report consumer self-reported adverse events. (21 C.F.R. § 803.50); and
- vi. Failed to report to the FDA a correction or removal conducted to reduce a risk to health posed by a device. (21 C.F.R. § 806.2(d), 10(a)(1)).

45. In that Letter, the FDA warned Medtronic “[y]our firm has several procedures for Medical Device Reporting and Adverse Drug Experience Reporting. These procedures, in turn reference several other procedures. You firm’s current problems regarding MDR reporting, as discussed above in this Warning letter, may be exacerbated by the complexity of your procedures and might have contributed to your firm’s deviations from the regulations regarding MDR reporting.”⁵

46. The FDA inspection also revealed several ongoing violations at Medtronic’s Minneapolis Plant’s Quality System that were noted in a Form 483, stating “[t]he specific violations noted in this letter and Form FDA 483 may be symptomatic of serious underlying problems in your firm’s manufacturing and Quality Assurance systems.” Specifically, the FDA warned that Medtronic:

- a. failed to achieve consistent compliance in areas such as design controls. (21 C.F.R. § 820.30); and

⁵ July 3, 2007 FDA Warning Letter, attached as Exhibit 4.

- b. failed to achieve consistent compliance in Corrective and Preventative Action (CAPA). (21 C.F.R. § 820.100).⁶

47. On June 1, 2009, the FDA issued a “Warning Letter” to Medtronic concerning their manufacturing facility in Juncos, Puerto Rico, detailing multiple violations of “Current Good Manufacturing Practice (CGMP) requirement of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.) part 820” based on inspections conducted in late 2008. Based upon those violations, the FDA determined that Medtronic’s SynchroMed® II Devices were “*adulterated*” within the meaning of 831(h) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. *et seq.* “in that the methods used in, or the facilities or controls used for, their manufacture, packing, sorting, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System regulation found at Title 21 Code of Federal Regulations (C.F.R.) Part 820.”⁷

48. The 2009 FDA Warning Letter concerning the Puerto Rico manufacturing plant specifically cited Medtronic for the following with regard to the SynchroMed® II Device:

- a. Failure to establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications, which shall include monitoring and control of process parameters and component and device characteristics during production;
- b. Failure to establish and maintain procedures for implementing corrective and preventive actions that include identifying the actions needed to correct and

⁶ *Id.*

⁷ June 1, 2009 FDA Warning Letter, attached as Exhibit 5.

prevent recurrence of non-conforming product and other quality problems as required by 21 C.F.R. § 820.100(a);

- c. Failure to establish and maintain procedures that ensure the Device History Records (DHRs) for each batch, lot or unit are maintained to demonstrate that the device is manufactured in accordance with the DHR as required by 21 C.F.R. § 820.184;
- d. Failure to review, evaluate and investigate complaint involving the possible failure of a device, labeling or packaging to meet any of its specifications as required by 21 C.F.R. § 820.198(c);
- e. Failure to report to FDA no later than thirty (30) calendar days after the day that Medtronic received or otherwise became aware of information from any source, that reasonably suggests that a device Medtronic marketed: 1) may have caused or contributed to a death or serious injury; or 2) has malfunctioned and this device or a similar device that Medtronic marketed would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur, as required by 21 C.F.R. § 803.50(a);
- f. Failure to have a person who is qualified to make a medical judgment reasonably conclude that a device did not cause or contribute to a death or serious injury, or that a malfunction would not likely to cause or contribute to a death or serious injury if it were to recur, as required by 21 C.F.R. § 803(c)(2); and
- g. Failure to ensure that persons qualified to make a medical judgment include physicians, nurses, risk managers, and biomechanical engineers under 21 C.F.R. § 803.20(c)(2): “[O]ur investigators determine that a product reporting specialist

was making decisions about MDR reportability for the Medtronic SynchroMed® II Implantable Pump Infusion System. The training record for this particular employee showed that this person only had a high school diploma with some additional in-house training.”⁸

49. At the time of inspection, the FDA informed Medtronic of the following manufacturing defects in the SynchroMed® II Device:

- a. Pumps manufactured without propellant. The FDA noted that while Medtronic *identified* this problem in May of 2006, and initiated a corrective and preventative action (CAPA) investigation in January 2007, Medtronic did not voluntarily recall the thirteen thousand five hundred fifteen (13,515) devices affected by this defect until May 2008, *a full two (2) years after the defect was identified*.
- b. Pumps did not show evidence of perforated septum;
- c. Pumps were missing a safety mechanism that served to assure that pumps are never overfilled; and
- d. *A critical step was left out of the manufacturing process*, which is the calculation of drug reservoir levels and drug dispensing rates. Despite numerous complaints that Medtronic received regarding accuracy rates, Medtronic failed to conduct any type of investigation into this problem.

50. The FDA determined that the SynchroMed® II Device was “***misbranded***” by virtue of the cited violation involving the failure or refusal to furnish material or information required under the statute and regulations relating to information that the devices may have either

⁸ *Id.*

caused or contributed to death or serious bodily injury, or malfunctions in such a way that if it were to recur would be likely to cause or contribute to a death or serious injury.

51. Additionally, while the FDA observed generally that the adequacy of Medtronic's responses could not be determined at the time, the FDA noted "the adequacy of your corrective and preventative measures will be determined during the next inspection." It specifically noted that Medtronic's response to the violation related to the "failure to establish and maintain procedures for implementing Corrective and Preventive Action (CAPA) procedures at [the Puerto Rico facility] will be conducted by July 31, 2009."⁹

52. In 2012, Medtronic's Minneapolis manufacturing plant was again inspected by the FDA. As a result of that inspection, the FDA issued a Warning Letter dated July 17, 2012 identifying Medtronic's specific violations of federal regulations in the manufacture of SynchroMed® II Devices including violations of CGMPs and Quality Systems requirements. The FDA informed Medtronic that the SynchroMed® II Devices, including the catheter, were "*adulterated.*"

53. The FDA cited Medtronic for incomplete complaint data and incorrect coding decision. The FDA stated this violation "may have compromised Medtronic's ability to detect and investigate [safety] signals."¹⁰

54. From February 14, 2013 through April 3, 2013, the FDA again inspected Medtronic's Neuromodulation manufacturing plant in Minneapolis. In April 2013, based on its inspection, the FDA informed Medtronic that the plant failed to manufacture devices that adequately conform to specifications and instead manufactured devices that are not adequately

⁹ *Id.*

¹⁰ July 17, 2012 FDA Warning Letter, attached as Exhibit 6.

controlled. Specifically, Medtronic failed to establish procedures for corrective and preventative action for problems including:

- a. “Feed through shorting” resulting in motor stalls, whereby at least two hundred ninety-eight (298) serious adverse events have resulted from this defect;
- b. Based upon a reported problem with their device, Medtronic failed to implement a recommendation from its Risk Evaluation Board and delayed any action taken. Since the decision to delay the action, at least thirty-seven (37) serious adverse events have been possibly related to the problem; and
- c. Medtronic detected signals showing a problem with catheter occlusion, but failed to update a Health Hazard Assessment for this defect since 2008, with over three hundred (300) complaints occurring since that time.¹¹

55. Further, the FDA notified Medtronic of the following:

Regulatory approval was received for Supplement 136 to PMA P860004 on December 15, 2011 to change the design of SC Catheter models 8709 SC, 8731 SC, 8596 SC, and Revision Kit model 8578 to mitigate a known field issue associated with CAPA 1507-SC Catheter Occlusion. This design change was implemented via ECO 12-00985, date March 6, 2012, and the new revisions of Catheter models were released to the field in September 2012. However, the previous SC catheter models which do not conform to the current design have continued to be distributed and have been attributed to 60 complaints of catheter occlusion since September 2012.¹²

D. SynchroMed® II Device recalls initiated by the U.S. Food & Drug Administration

56. Since 2008, the FDA has issued nineteen (19) Class I Recall Actions for the SynchroMed® II Device. A recall is an action taken to address a problem with a medical device

¹¹ FDA Form 483, Inspection Observations, Dated Feb. 14, 2013 – April 3, 2013, attached as Exhibit 7.

¹² *Id.*

that violates federal law. Recalls occur when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health.

57. A Class I recall is the most serious recall category issued when there is a probability that the use of the product could cause serious health consequences or death. Any drug or medical device that has been the subject of a Class I recall can be deadly or cause serious life-long injury.

58. Up to December 13, 2012, The Class I and Class II recalls issued for the SynchroMed® II Device include, but are not limited to:

- a. Formation of inflammatory masses near the tip of the intrathecal catheters (Class I, March 22, 2008);
- b. Pumps manufactured without propellant (Class II, September 3, 2008);
- c. Battery failure (Class II, September 29, 2009);
- d. Inadequate instruction for filling/refilling of pumps causing injection of all or some of the prescribed drug into the patient's subcutaneous tissue (Class I, August 29, 2011);
- e. Reduced battery performance leading to sudden loss of therapy (Class I, August 29, 2011);
- f. Software failure resulting in incorrectly displayed "scheduled to replace the pump by" date (Class II, March 30, 2012); and
- g. Use of unapproved (off-label) drugs in the pumps leading to permanent motor stall and cessation of infusion (December 13, 2012).

59. On June 3, 2013, the FDA issued two (2) Class I recalls related to the Medtronic SynchroMed® II Implantable Infusion Pump System.

a. The first 2013 recall covers all of the SynchroMed® II pumps implanted worldwide manufactured from May 1998 through June 2013 and distributed from April 1999 through June 2013. In the letter, the FDA warned that the following would happen with the defective pumps:

- i. Unintended delivery of drugs during the priming bolus procedure can result in drug underdelivery and overdelivery, leading to respiratory depression, coma or death, and
- ii. Potential for electrical shorting, internal to the SynchroMed® II infusion pump, leading to a loss of or reduction in therapy, resulting in serious adverse health consequences including death. At the time of the 2013 recalls, there were two hundred sixty-one thousand, one hundred nine (261,109) SynchroMed® II Implantable Infusion Pumps System implanted worldwide.

b. The second 2013 recall affects *all Sutureless Connector Intrathecal Catheters* in the SynchroMed® II Device, Models #8709SC, 8731SC, and Sutureless Revision Kits, Models #8596SC, and 8578 with a “use by” date of August 25, 2014. Both of Mr. White’s failed intrathecal catheters were Models 8709SC and included within this recall. In the recall, the FDA noted the reasons for the recall:

- i. “The sutureless Connector Intrathecal Catheter connector has been redesigned to reduce the potential for occlusion, which is the blockage or stoppage of drug flow due to misalignment at the point where the catheter connects to an implantable pump. Medtronic is removing all unused products that were manufactured with the previous design.

Medtronic recommends the previous design of Sutureless connector Intrathecal Catheter Products no longer be used due to greater potential for misalignment and subsequent occlusion.”

- ii. “This product may cause serious adverse health consequences, including drug under dose, loss of symptom relief, drug withdrawal symptoms caused by the lack of drug delivery to the intrathecal space, and/or death.”

E. The United States of America files a Complaint for Permanent Injunction against Medtronic, Inc. and individuals S. Omar Ishrak and Thomas M. Tefft

60. On April 27, 2015, the United States Department of Justice and United States Department of Health and Human Services filed a Complaint for Permanent Injunction against Medtronic, Inc. and S. Omar Ishrak and Thomas M. Tefft with respect to their manufacture of the SynchroMed® II Device.¹³

61. The Complaint alleges that Medtronic, S. Omar Ishrak, and Thomas M. Tefft “are well aware that their practices violate the Act. FDA has repeatedly warned Defendants, both orally and in writing, about their violative conduct, and has emphasized the importance of Defendants’ compliance with the Act.”

62. In addition to the cited Warning Letters, the Complaint alleges that representatives of Medtronic attended a meeting with FDA’s Center for Devices and Radiological Health and Minneapolis District Office on January 31, 2013. At this meeting, *“Defendants stated that they were aware of the violations at their facilities and were taking steps to correct them.”*

¹³ See Exhibit 2.

63. The Complaint further alleges Medtronic made promises to correct their violations in written responses to each inspection; however, the Complaint alleged that none of the responses contained adequate evidence that Medtronic corrected their deviations.

64. The United States Attorney stated in the Complaint that, “[b]ased upon Defendants’ conduct, Plaintiff believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a) and (k) [introducing into interstate commerce any article of device that is **adulterated**, or causing any article of device to become **adulterated** within the meaning of 21 U.S.C. § 351 (h) while such devices are held for sale after shipment in interstate commerce].”

65. The United States of America’s Complaint requested a permanent injunction to restrain Medtronic, in their manufacture of the SynchroMed® II Device, from their continued violation of federal regulations, and,

That the Court order Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, to cease directly and indirectly manufacturing, packing, labeling, and distributing (domestically and internationally) SynchroMed II implantable infusion pumps at or from its Medtronic’s Neuromodulation facilities, unless and until Defendants’ methods, facilities, and controls used to manufacture, process, pack, label, hold and distribute the SynchroMed II implantable infusion pumps are established, operated, and administered in compliance with 21 USC 360j(f)(1) and the Quality System regulation prescribed in 21 C.F.R. Part 820, and in a manner that has been found acceptable to FDA.¹⁴

66. On April 27, 2015, United States District Court Judge Joan N. Erickson signed a Consent Decree of Permanent Injunction against Medtronic preventing the manufacture and

¹⁴ *Id.*

distribution of the Medtronic SynchroMed® Implantable Infusion Pump systems in violation of the terms of the Consent Decree.¹⁵

67. Under the Consent Decree, Medtronic is “permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a), from directly or indirectly designing, manufacturing, processing, packing, labeling, holding, storing, and distributing, importing into or exporting from the United States of America, at or from any Medtronic Neuromodulation facilities, any model of, or components or accessories for, its SynchroMed devices.” Under the Consent Decree, the permanent injunction would be lifted only in the event that Medtronic complies with a series of enumerated requirements to ensure that it would cease violating federal law in the production of its SynchroMed® II Device.

68. Upon information and belief, Medtronic continues to produce, distribute, and sell their SynchroMed® II Device in violation of the Decree.

IV. CAUSES OF ACTION

COUNT I **MANUFACTURING DEFECT**

69. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

70. The SynchroMed® II Device implanted in Jordan White’s abdomen was manufactured in violation of the Federal Food, Drug, and Cosmetic Act and federal regulations promulgated pursuant to it. The SynchroMed® II Device implanted in Mr. White’s abdomen was manufactured in violation of Pennsylvania law that parallels federal requirements set forth herein.

¹⁵ Consent Decree of Permanent Injunction, attached as Exhibit 8.

71. As a result of Medtronic's violations of federal statutory and regulatory standard of care and device specific regulations, the SynchroMed® II Device implanted in Jordan White's abdomen failed and required revision and removal surgeries.

72. At the time the SynchroMed® II Device implanted into Jordan White's abdomen left the control of Medtronic, it was unreasonably dangerous due to Medtronic's violations of the Federal Food, Drug, and Cosmetic Act, and the regulations promulgated pursuant to it in one or more of the following ways:

- a. The SynchroMed® II Device was introduced or delivered for introduction into interstate commerce as **adulterated** in violation of 21 U.S.C. §§ 331, 351(h) and 21 C.F.R. Part 820;
- b. The SynchroMed® II Device was **adulterated** in interstate commerce in violation of 21 U.S.C. §§ 331, 351 (h) and 21 C.F.R. Part 820;
- c. The SynchroMed® II Device was received in interstate commerce **adulterated** and was delivered for pay or otherwise, in violation of 21 U.S.C. §§ 331, 351(h) and 21 C.F.R. Part 820; and
- d. The SynchroMed® II Device implanted in Jordan White was **adulterated** because it was manufactured in deviation from the manufacturing specifications approved by the FDA in Medtronic's PMA application in violation of the Federal Food, Drug, and Cosmetic Act.

73. Defendants are medical device companies engaged in the design and/or research and/or manufacture and/or production and/or testing and/or assembling and/or labeling and/or packaging and/or distribution and/or sale and/or otherwise involved in placing in the stream of commerce various medical devices, as hereinbefore set forth, intended for human use including

facilitating the infusion and/or consumption and ingestion of pharmaceutical products for the treatment of specific medical conditions.

74. At all times relevant hereto, Defendants, and each of them, held themselves out as knowledgeable and possessing the requisite skill peculiar to the research and/or manufacture and/or production and/or testing and/or assembling and/or labeling and/or packaging and/or distribution and/or sale of such product(s).

75. At all times relevant hereto, federal law required Defendants to manufacture the SynchroMed® II Device in compliance with federal specifications and requirements imposed through the PMA process for the device, and in compliance with post-approval federal regulations, including but not limited to those set out in 21 C.F.R. § 801, *et seq.*, 21 C.F.R. 803, *et seq.*, 21 C.F.R. § 814, *et seq.*, 21 C.F.R. § 806, *et seq.*, 21 C.F.R. § 820, *et seq.*, and 21 U.S.C. §§ 351-352. Such regulations are promulgated to ensure a manufactured device is free from a defective condition unreasonably dangerous to the consumer.

76. At the times relevant hereto, as a manufacturer of a medical device, under Pennsylvania law, Defendants were required to use reasonable care in the manufacture, assembly, inspection, packaging, testing of SynchroMed® II Device to protect users such as Jordan White. Reasonable care under the circumstances for a device manufacturer would include complying with federal regulations designed to ensure the safe manufacture, assembly, inspection, packaging, and testing of medical devices.

77. Defendants breached their duty under Pennsylvania law in that they failed use reasonable care to ensure that Jordan White's SynchroMed® II Device complied with federal requirements, manufactured Jordan White's SynchroMed® II Device in a way that did not comply with their federal requirements, and failed to test and inspect the SynchroMed® II

Device before placing it into the stream of commerce and made it available for sale to Mr. White. In so doing, Defendants failed to comply with manufacturing requirements imposed by the Device's PMA requirements and post-approval regulations.

78. Specifically, as evidenced by the August 29, 2006 FDA Warning Letter,¹⁶ Medtronic committed "significant deviations" in the manufacture of Jordan White's catheters in his SynchroMed® II Device.

79. The Warning Letter which was "not intended to be an all-inclusive list of deficiencies at your facility" put Medtronic on notice of significant and substantially similar problems with failures in their intrathecal catheters in which Medtronic:

- a. Failed to validate the design for the catheter bond tip;
- b. Failed to ensure the catheter complied with specifications for the manufacture of the Device;
- c. Failed to investigate the cause of non-conforming catheters;
- d. Failed to implement changes needed to correct and prevent quality problems in the catheter;
- e. Failed to ensure that the finished devices (catheters) were "safe and effective" and otherwise in compliance with the Federal Food, Drug and Cosmetic Act"; and
- f. Based upon the "out-of-specifications" manufacture of Jordan White's SynchroMed® II Device, the FDA determined that his catheters as manufactured by Defendants, were "adulterated."

80. Jordan White suffered injury due to two non-conforming, adulterated, and defective intrathecal catheters in his SynchroMed® II Device. These catheters were noted by his

¹⁶ See Exhibit 3.

physicians to be occluded and broken, thereby resulting in the overdelivery and/or underdelivery of medication to Mr. White and resultant severe injury.

81. As a result of Medtronic's failure to use reasonable care in complying with federal law in the manufacture of Jordan White's SynchroMed® II Device, Jordan White's catheters were manufactured out of specification, were non-conforming, adulterated, and had the propensity for fracturing and occlusion and did fracture, break, and occlude.

82. As a foreseeable, direct and proximate result of Defendants' negligence in manufacturing Jordan White's SynchroMed® II Device, Mr. White experienced severe pain and suffering which continues through present day and will continue into the future, multiple surgical procedures to correct the defects in his SynchroMed® II Device, extensive hospitalization and medical procedures, and other damages compensable by law.

COUNT II
FAILURE TO WARN

83. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

84. Defendants are medical device entities engaged in the design and/or research and/or manufacture and/or production and/or testing and/or assembling and/or labeling and/or packaging and/or distribution and/or sale and/or otherwise placing into the stream of commerce various medical devices intended for human use, including the SynchroMed® II Device, which is a surgically implanted device that delivers medication into the intrathecal space of patients for the treatment of chronic pain, and as an alternative to oral pain medication.

85. At all times relevant hereto, Medtronic had a continuing duty to monitor the SynchroMed® II Device placed into the stream of commerce, to discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which

Medtronic became aware, and that are or may be attributable to the product. (FD&C Act, Medical Device Reporting Title 21, Code of Federal Regulations (C.F.R.), Part 803)) “[R]equires manufacturers, distributors, and initial distributors of medical devices to establish, maintain a record of and report the result to FDA certain adverse events that they receive from any source, and to establish and maintain reports.”

86. At all times relevant hereto, under Pennsylvania law, Defendants had a duty to disclose to users and purchasers, including the FDA, of potentially dangerous risks involved in their product’s use. Such duty imposes an obligation on Medtronic to timely inform the FDA when Medtronic learned of the propensity for a catheter malfunction.

87. Medtronic breached their duty under federal and Pennsylvania law, in that it:

- a. Failed to report problems with devices, including catheter separation or fracture;¹⁷
- b. Failure to report consumer generated adverse events;
- c. Failed to report that in 2008, Medtronic detected a “signal” showing a problem with catheter occlusion in the SynchroMed® II Device, but failed to update a Health Hazard Assessment for this defect until 2011;¹⁸
- d. Failed to report under 21 CFR 803, a “malfunction” event for an adverse event, such as when a catheter fractures;¹⁹ and
- e. Failed to submit FDA-mandated Medical Device Reports (MDRs) within 30 days of becoming aware that the SynchroMed® II Device (including the catheter)

¹⁷ See Exhibit 4.

¹⁸ *Id.*

¹⁹ *Id.*

caused or contributed to a death or serious injury, under 21 C.F.R. § 803.50(a)(1), thereby resulting in the devices being “misbranded.”²⁰

88. Medtronic knew at all times before Jordan White was implanted with his original SynchroMed® II Device, that the catheter he received was defective in that the catheter failed due to a high rate of occlusion, fracture, breakage, and obstruction, yet it failed to inform the FDA of the danger.

89. Because Medtronic failed to comply with their duty under federal law, they breached their “duty to use reasonable care” under Pennsylvania law to disclose material risks of the SynchroMed® II Device to the FDA and the public, including Jordan White. This duty parallels Medtronic’s requirements under federal law to timely and properly report adverse events and safety issues relating to the SynchroMed® II Device.

90. Had the FDA been properly and timely warned of the high failure rates of the intrathecal catheters, Jordan White and his medical providers would have learned of the high failure rates of catheters and heeded that warning, thereby avoiding use of the intrathecal catheters.

91. As a foreseeable, direct and proximate result of Medtronic’s failure to warn, as set forth above, about the defective condition of the SynchroMed® II Device, Jordan White experienced severe pain and suffering which continues through present day and will continue into the future, multiple surgical procedures to correct the defects in his SynchroMed® II Device, extensive hospitalization and medical procedures, and other damages compensable by law.

²⁰ *Id.*

COUNT III
NEGLIGENCE

92. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

93. Defendants, and each of them, are medical device entities engaged in the design and/or research and/or manufacture and/or production and/or testing and/or assembling and/or labeling and/or packaging and/or distribution and/or sale and/or otherwise placing into the stream of commerce various medical devices intended for human use, including the SynchroMed® II Device, which is a surgically implanted device that delivers medication into the intrathecal space of patients for the treatment of chronic pain, and as an alternative to oral pain medication.

94. At all times relevant hereto, Defendants manufactured, distributed and sold Jordan White's SynchroMed® II Device, comprising of a pump and catheter. Mr. White used his SynchroMed® II Device as intended by the Medtronic.

95. Under Pennsylvania law, every manufacturer, including Medtronic has a duty to use reasonable care to avoid foreseeable dangers in their products. Specifically, Medtronic at all relevant times hereto had a duty to use reasonable care in the manufacturer, testing, monitoring, inspection, assembly, and sale of Jordan White's SynchroMed® II Device. Such duties are parallel to those imposed under federal law.

96. Federal law imposes post-market requirement on Medtronic, including those found under 21 C.F.R. § 820, *et seq.*, which promulgates Current Good Manufacturing Practices (CGMPs). The quality control requirements of the CGMPs are designed to ensure Medtronic's products conform to manufacturing specifications, that non-conforming products do not reach the market, and that problems with products in the field are properly monitored, tracked and

reported. The CGMPs require Medtronic to evaluate signals of unexpected or serious events of injury in the field and report to the FDA when a device causes, or is suspected to cause, injury in the field. A device that has been manufactured, monitored, packed, stored, inspected, or installed in violation of this requirement is deemed to be adulterated. 21 C.F.R. § 351 (h). A manufacturer is prohibited from introducing, delivering, or selling an adulterated device into interstate commerce. 21 C.F.R. § 331(a),(k).

97. As a result of numerous FDA inspections from 2006-2013 to Medtronic's manufacturing plants in Minneapolis, Minnesota and Juncos Puerto Rico, as alleged herein, the FDA determined the SynchroMed® II Device and, in particular, the intrathecal catheters implanted in Jordan White's body, were "adulterated" and "misbranded" and thereby violated specific CGMPs as outlined *supra* in paragraphs herein.

98. Medtronic violated their duty to comply with their obligations to manufacture their SynchroMed® II Device in conformity with CGMPs and therefore could not ensure the safety and effectiveness of the SynchroMed® II Device received by Jordan White.

99. As a foreseeable, direct and proximate result of the Medtronic's failure to use due care to avoid foreseeable dangers in their SynchroMed® II Device, Jordan White's SynchroMed® II Device was manufactured out of specification and was misbranded and adulterated in violation of federal law.

100. As a further foreseeable, direct and proximate result of Medtronic's failure to use due care to avoid foreseeable dangers in their SynchroMed® II Device, Jordan White's nonconforming Device failed to deliver medication into his intrathecal space at the programmed rate, causing severe pain and suffering which continues through present day and will continue into the future, multiple surgical procedures to correct the defects in his SynchroMed® II

Device, extensive hospitalization and medical procedures, and other damages compensable by law.

COUNT IV
NEGLIGENCE PER SE

101. Plaintiff incorporates by reference as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

102. Under Pennsylvania law, a manufacturer has a duty to follow product safety regulations, and a violation of Food Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, establishes negligence per se and causes products to be defective as a matter of law.

103. The purpose of the Federal Food, Drug & Cosmetic Act is to protect consumers such as Jordan White from physical injury when they use a medical device. The injuries suffered by Mr. White are the types of injuries against which the Act is meant to protect.

104. Medtronic breached this duty in that it violated, pursuant to the above identified Warning letters, FDA Form 483, and Inspection Reports, the provisions of the Food Drug and Cosmetic Act, including but not limited to the following “significant deviations” from CGMP’s while manufacturing their catheters in that Medtronic:

- a. Failed to ensure the catheter complied with specifications for the manufacture of the device;
- b. Failed to investigate the cause of non-conforming catheters;
- c. Failed to implement changes needed to correct and prevent quality problems in the catheter;
- d. Failed to ensure that the finished catheters were “safe and effective” and otherwise in compliance with the Federal Food, Drug and Cosmetic Act;

- g. Manufactured Jordan White's intrathecal catheter outside of specifications set forth in applicable federal requirements, resulting in the FDA's determination that the Mr. White's catheter as manufactured by Defendants was "adulterated;"²¹ and
- h. Failed to update a Health Hazard Assessment for the 8709SC catheter related to catheter occlusion.²²

105. As a result of the deviations from specifications and violations of federal law, Medtronic manufactured catheters with a propensity for occlusion, breakage, and fracturing. Such catheters were implanted in Jordan White's body and failed during their normal use, which prevented delivery of medication to Mr. White's intrathecal space at the programmed rate and prevented the treatment the device was designed to provide.

106. Because his SynchroMed® II Device could no longer effectively deliver medication to the treatment site in a safe manner, Jordan White's SynchroMed® II Device caused significant injuries and required revision and ultimately removal.

107. As a foreseeable, direct and proximate result of Medtronic's negligence per se, Jordan White experienced severe pain and suffering which continues through present day and will continue into the future, multiple surgical procedures to correct the defects in his SynchroMed® II Device, extensive hospitalization and medical procedures, and other damages compensable by law.

COUNT V
BREACH OF EXPRESS WARRANTY

108. Plaintiff incorporates by reference as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

²¹ See Exhibit 6.

²² See Exhibit 7.

109. At all times relevant hereto, Medtronic expressly warranted and promised by way of written literature, advertisements, and/or other documents and/or promotional materials directed to Jordan White and his medical providers, that despite the significant cost difference in therapy, the use of an implanted SynchroMed® II Device designed to deliver medication to the intrathecal space was a superior and safer method than oral medication and/or alternative means of therapy to treat his muscle spasticity.

110. Jordan White and his medical providers received, heard, and/or read Medtronic's express warranties that the SynchroMed® II Device conformed to FDA regulations and specifications, and was safe, effective, and fit and proper for its intended uses and foreseeable uses.

111. Based upon Medtronic's representations of the significant benefits of the SynchroMed® II Device as compared to other forms of baclofen delivery or treatment for muscle spasticity, Jordan White purchased and underwent surgery for implantation of the SynchroMed® II Device.

112. Jordan White and his medical providers received, heard, and/or read Medtronic's express warranties that the SynchroMed® II Device conformed to FDA regulations and specifications, and was safe, effective, and fit and proper for its intended uses and foreseeable uses.

113. Jordan White and his medical providers relied upon Medtronic's express warranties that the SynchroMed® II Device conformed to FDA regulations and specifications, and was safe, effective, and fit and proper for its intended uses and foreseeable uses, when in fact it was manufactured in violation of federal regulations and specifications and was unsafe and unfit for such uses.

114. Defendants breached their express warranties because the warranty and representations were untrue in that:

- a. The FDA had determined that the Medtronic SynchroMed® II Device implanted in Jordan White was manufactured in violation of federal regulations and specifications, including CGMPs;
- b. The FDA violations of CGMPs committed by Medtronic meant that Medtronic was unable to confirm that the SynchroMed® II Device implanted in Jordan White was safe and effective, fully conformed to specifications, and was free of defects that could lead to malfunctions having the potential to cause or contribute to serious bodily injury; and
- c. The FDA had determined that the SynchroMed® II Device implanted in Jordan White was manufactured at a time when SynchroMed® II Devices were labeled “adulterated” and “misbranded.”

115. The implanted SynchroMed® II Device’s intrathecal infusion delivery of pain medication is not a superior method to oral medication or alternative therapy to treat muscle spasticity.

116. As a result of the aforementioned breach of their express warranties by Medtronic, Jordan White experienced severe pain and suffering which continues through present day and will continue into the future, multiple surgical procedures to correct the defects in his SynchroMed® II Device, extensive hospitalization and medical procedures, and other damages compensable by law.

COUNT VI
BREACH OF IMPLIED WARRANTIES

117. Plaintiff incorporates by reference as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

118. Prior to purchasing the Medtronic's SynchroMed® II Device, Defendants provided Jordan White and his physicians written advertising materials (which were not part of the pre-approval process) describing the SynchroMed® II Device as a better alternative to receiving oral medications in that it was:

- a. "a safer way to receive pain medication";
- b. "Help you rejoin life so you can get back to the activities and people that make you happiest";
- c. "allows you to 'Tame your Pain'";
- d. "reduce your need for oral medications";
- e. "provide peace of mind knowing that you've selected a drug delivery system that was manufactured by Medtronic . . .";
- f. "give reassurance because only Medtronic offers a programmable drug delivery system that is FDA approved for MRI scans . . .";
- g. "drug delivery therapy from Medtronic is proven safe and effective therapy";
- h. "Medtronic drug delivery therapy has been tested, is shipped sterile, and is FDA approved"; and
- i. "More doctors trust Medtronic than any other company offering drug delivery therapy."

119. Jordan White and his physicians relied on the written advertisements of Medtronic related to the SynchroMed® II Device, leading to the implantation of the Device into Jordan White's body.

120. The SynchroMed® II Device implanted in Jordan White failed to perform its essential purpose, which was to deliver programmed baclofen medication into his intrathecal space.

121. Jordan White's SynchroMed® II Device, which lacked a catheter free from defect, was not reasonably fit for ordinary use or use in the manner ordinarily contemplated. Accordingly, Medtronic breached its implied warranty of merchantability with respect to Jordan White's SynchroMed® II Device.

122. At the time and place that Jordan White purchased and used the SynchroMed® II Device, Mr. White relied upon Medtronic's implied warranties, not knowing that Medtronic knew, that in fact the SynchroMed® II Device was unfit and unsafe for its ordinary use, and had been found by the FDA to be "**adulterated**" and "**misbranded**" in that it was not manufactured, and/or packaged, and/or labeled in accordance with FDA regulations, did not perform in accordance with approved specifications, and was therefore not safe nor effective for the intended, known, or foreseeable uses, nor of merchantable quality, as warranted by Medtronic.

123. As a result of Medtronic's aforementioned breach of their implied warranties, Jordan White, after purchasing and being implanted with, and utilizing Medtronic's non-conforming, defective products, experienced severe pain and suffering which continues through present day and will continue into the future, suffered multiple surgical procedures to correct the defects in his SynchroMed® II Device and extensive hospitalization and medical procedures.

COUNT VII
NEGLIGENT MISREPRESENTATION

124. Plaintiff incorporates by references, as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

125. At all times relevant hereto, Medtronic had a duty under Pennsylvania law to advertise and represent correct information regarding the SynchroMed® II Device, as such information involves public welfare and safety.

126. At all times relevant hereto, Defendants negligently misrepresented to Jordan White and his medical providers that the SynchroMed® II Device implanted in Mr. White was safe and effective, despite knowing that the SynchroMed® II Device was defective and capable of causing the injuries described herein.

127. Defendants made the aforesaid representations with no reasonable ground for believing them to be true when Defendants possessed data showing the SynchroMed® II Device to be defective and dangerous when used in the intended manner.

128. The aforesaid representations were made to the medical providers prescribing the SynchroMed® II Device prior to the dates prescribed to Jordan White and used by Mr. White's medical providers with the intent that Jordan White and his medical providers rely upon such misrepresentations about the safety and efficacy of the SynchroMed® II Device.

129. Defendants failed to use reasonable care or competence in obtaining the information or communicating it to Jordan White and his medical providers.

130. Jordan White and his medical providers reasonably and justifiably relied upon such representations provided by Defendants that the SynchroMed® II Device was safe for use for the prescribed and intended purposes.

131. Representations and communication by Defendants to Jordan White and his medical providers were false, and thereby caused Jordan White's injuries described herein, harming Mr. White as a result of the false representations of Defendants.

COUNT VIII
VIOLATION OF PENNSYLVANIA'S UNFAIR TRADE PRACTICES AND CONSUMER PROTECTION LAW

132. Plaintiff incorporates by references, as if fully set forth herein, each and every allegation contained in the preceding paragraphs of this Complaint.

133. By reason of the conduct alleged herein, Defendants violated Pennsylvania's Unfair Trade Practices and Consumer Protection Law (UTPCPL), 73 P.S. 18§ 201-1, et seq., by engaging in fraudulent and deceptive conduct which created a likelihood of confusion and/or misunderstanding.

134. At all times relevant hereto, Defendants knowingly and intentionally induced Jordan White to use the SynchroMed II Device through the use of false and or/misleading representations and statements.

135. The SynchroMed II Device failed to perform as represented and, in fact, was unsafe.

136. Defendants induced Jordan White and his physicians, through the use of false and/or misleading advertising, representations, and statements, as described above, to use and/or implant the SynchroMed II Device, which Defendants manufactured and/or distributed and sold, all in violation of the UTPCPL, which proscribes, among other things:

- a. Engaging in unfair trade practices as defined in the statute by making false and misleading oral and written statements that have the capacity, tendency, or effect of deceiving or misleading consumers;

- b. Engaging in unfair trade practices as defined in the statute by making representations that its SynchroMed II Device had an approval, characteristic, use, or benefit which it did not have, including but not limited to statements concerning the consequences of the use of the SynchroMed II Device;
- c. Engaging in unfair trade practices as defined in the statute by failing to state material facts, the omission of which deceived or tended to deceive, including but not limited to facts relating to the health consequences of the use of the SynchroMed II Device; and
- d. Engaging in unfair trade practices as defined in the statute through deception, fraud, misrepresentation, and knowing concealment, suppression, and omission of material facts with the intent that consumers rely upon the same in connection with the use and continued use of the SynchroMed II Device.

137. As a foreseeable, direct and proximate result of Defendants' statutory violations, Jordan White had the SynchroMed II Device implanted, which he would not have had implanted had Defendants not issued false and/or misleading advertisements, representations, and statements.

138. By reason of such violations and pursuant to the laws and regulations of this state, Plaintiff is entitled to recover all of the monies paid for the products; to be compensated for the cost of medical care arising out of the use of the SynchroMed II Device; together with any and all actual damages recoverable under the law including, but not limited to, past medical expenses, past pain and suffering, disability, and emotional distress.

139. In addition, Plaintiff is entitled to recover fees and disbursements, including costs of investigation, reasonable attorneys' fees, and any other equitable relief as determined by this Court.

V. PUNITIVE DAMAGES

140. Defendants, through their agents, committed the acts alleged herein outrageously, maliciously, willfully, because of Defendants' evil motive or reckless indifference to the rights of others, including Jordan White. Defendants received information that long term use of SynchroMed® II Device increased the likelihood of drug under- and overdose, leading to respiratory depression, coma or death and potential for electrical shorting, leading to a loss of or reduction in therapy, resulting in serious adverse health consequences including death and other injuries, but despite this information continued to intentionally and falsely represent that using SynchroMed® II Device was safe. Defendants failed to issue warnings until the incident rate of injury was so high. Even after that time, Defendants downplayed the adverse effects of the SynchroMed® II Device, and misinformed and continued to promote the SynchroMed® II Device to the public. Defendants did so in order to preserve the lucrative and growing market they had carefully built with deception. The failure to inform doctors and their patients of material risks of the SynchroMed® II Device was intentional. Defendants acted with greed and other improper and evil motives amounting to malice, and in conscious disregard of Jordan White's rights. The acts taken toward Jordan White were carried out in a deliberate and intentional or grossly reckless manner with malice and without regard of the likelihood that Defendants' products would injure and damage Mr. White and others. Plaintiff is entitled to recover punitive damages from Defendants in an amount according to proof.

VI. PRAYER FOR RELIEF

Plaintiff hereby requests a trial by jury on all claims and issues so triable.

WHEREFORE, Plaintiff demands judgment against Defendants in an amount of damages in excess of seventy-five thousand dollars (\$75,000.00), individually, jointly, severally, and in the alternative, including:

1. Awarding actual damages to Plaintiff incidental to the purchase and use of the products at issue in an amount to be determined at trial;
2. Awarding the past and future costs of treatment for Jordan White's injuries caused by the products at issue in an amount to be determined at trial;
3. Awarding damages for Jordan White's physical pain and suffering in an amount to be determined at trial;
4. Awarding damages for Jordan White's mental and emotional anguish in an amount to be determined at trial;
5. Awarding damages for Jordan White's loss of earnings and future earning capacity;
6. Awarding pre-judgment and post-judgment interest to Plaintiff;
7. Awarding injunctive relief, including disgorgement of all profits made from and monies from and monies paid for the products at issue in an amount to be determined at trial;
8. Awarding punitive and/or exemplary damages;
9. Awarding the costs and expenses of this litigation incurred by Plaintiff;
10. Awarding reasonable attorneys' fees and costs to Plaintiff as provided by law;
11. Awarding civil penalties for statutory violations as claimed above; and

12. Any other further relief in law or equity that this Court deems appropriate, necessary, just, and proper.

Respectfully submitted by:



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